



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,920	03/22/2001	Sherman Fong	P1192-2	6172

9157 7590 11/06/2002

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 11/06/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,920

Applicant(s)

FONG ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-14,22-27 and 32-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 15,17,19-21 and 28-31 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The information disclosure statement filed 05 October 2001 (Paper No. 6) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The amendment filed 21 June 2002 (Paper No. 8) has been entered in full. Claim 18 was cancelled. Applicant's election without traverse of Group II (claims 15-17, 19-21, 27(a), 28-31(a)) and SEQ ID NO:2 in Paper No. 8 is acknowledged.

Claims 1-14, 22-26, 32-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. This occurs on page 10, line 30; page 13, line 14 and page 65, line 23. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 27, 29, 30 and 31 are objected to because of the following informalities:

Claims 27, 29, 30 and 31 encompass non-elected inventions and require amendment to limit to elected invention. Applicant is required to cancel the claim(s), or

Art Unit: 1647

amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 15,17, 19, 20, 27-31 rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al., U.S. Patent No. 5,910,431. The instant claims are generally drawn to the isolated Bolekine polypeptide consisting of amino acids residues 1 or *about* 34 to *about* 111 of Figure 2 (SEQ ID NO:2) and an isolated Bolekine polypeptide *comprising* the sequence of amino acid residues from 1 or *about* 34 to *about* 111 of Figure 2 (SEQ ID NO:2) or a fragment thereof sufficient to provide a binding site for an anti-Bolekine antibody.

Ni teaches an amino acid sequence which is 100% identical to amino acids 1-107 of SEQ ID NO:2, therefore Ni teaches a sequence consisting of amino acid residues from 1 or about 34 to about 111 of SEQ ID NO:2 and fragments thereof

Art Unit: 1647

sufficient to provide a binding site for an anti-Bolekine antibody. Please see sequence query Appendix A.

Ni teaches various tags (Please see reference, column 10, lines 58-67; column 11, lines 1-12) and fusion proteins of the instant invention (column 20, lines 50-63). Ni teaches antibodies to the polypeptide or fragments thereof (i.e. epitopes)(column 24, lines 50-67, column 25, lines 1-23). Ni teaches that the invention may be employed to stimulate wound healing, both via the recruitment of debris clearing and connective tissue promoting inflammatory cells (column 25, lines 48-54). Ni teaches that the invention may also be employed to inhibit T cell proliferation by the inhibition of IL-2 biosynthesis for the treatment of T-cell mediate auto-immune diseases (column 25, lines 44-47). Ni teaches a therapeutically effective amount of the polypeptide and a pharmaceutically acceptable carrier (column 28, lines 43-55). Ni teaches kits comprising one or more containers filled with the invention (column 28, lines 56-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni *et al.* U.S. Patent No. 5,910,431 in view of Boyle U.S. Patent No. 5,843,678. The teachings of Ni *et al.* are described above in the 102(e) rejection. Ni does not teach an Fc region of an immunoglobulin. Boyle teaches a fusion between a polypeptide and an Fc region of an immunoglobulin (column 2, lines 20-29 and lines 62-66; column 3, lines 1-5 and lines 21-23; column 10, lines 17-26 and column 11, lines 46-64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ni and Boyle to make the instant invention. The motivation and expected success is provided by the teachings of Boyle regarding the Fc region. The Fc region will aid in purification of the protein and stability.

Matter of Record

Strachan, U.S. Patent No. 6,150,502 disclosed a polypeptide sequence which is 100% identical to the sequence comprising SEQ ID NO:2 of the instant application.

Conclusion

Claim 16 is allowed.

Art Unit: 1647

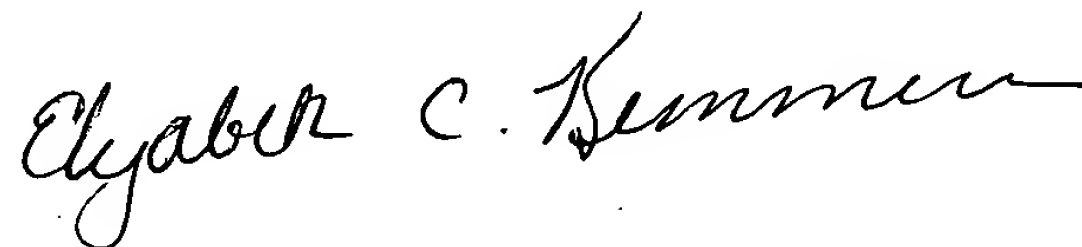
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
November 1, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER